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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,137	09/12/2003	Jeffrey R. Fine	18205-00002	9088
7590	06/07/2006		EXAMINER	
MIRICK O'CONNELL 1700 WEST PARK DRIVE WESTBOROUGH, MA 01581-3941			SPIVACK, PHYLLIS G	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 06/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/662,137	FINE, JEFFREY R.	
	Examiner Phyllis G. Spivack	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 23 March 2006.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

Applicant's Response filed March 24, 2006 is acknowledged. Claims 1-20 remain under consideration.

A spelling correction is noted on page 6 of the specification for the term "phenylpropanolamine."

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Claims 1 and 13 have been amended to recite "relieving the potential for" symptoms of ear and sinus cavity blockage. The claims were previously drawn to alleviating the symptoms of ear and sinus cavity blockage, conditions that have occurred.

The present claims have been amended from conditions that have occurred to conditions that may occur. The specification does not describe and does not support the amendment to claims 1 and 13 drawn to "relieving the potential for" symptoms of ear and sinus cavity blockage.

In the last Office Action claims 1-20 were rejected under 35 U.S.C. 103(a) as being unpatentable over both Jones et al., American Journal of Emergency Medicine, and Singletary et al., American Journal of Emergency Medicine. It was asserted Jones teaches the administration of two decongestants, oral pseudoephedrine and topical oxymetazoline, in the **prevention** of middle ear barotrauma. The present specification teaches equivalence among the recited decongestants in alleviating the

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symptoms of ear and sinus cavity blockage in a descending aircraft. Singletary teaches combination therapy in the form of both systemic and topical decongestants to treat a patient suffering from symptoms of sinus cavity blockage during airline descent.

Applicant argues the subjects in the Jones reference took either an oral decongestant or a topical decongestant with the nasal spray being "little more effective than placebo". Further, Applicant argues Singletary does not describe a prophylactic regimen. Applicant urges the references fail to teach administration before landing.

Applicant's arguments have been given careful consideration but are not found persuasive. The rejection of record under 35 U.S.C. 103 is maintained for the reasons of record. In the first sentence of the Abstract, Jones refers to the prevention of middle ear barotrauma during air travel through the administration of an oral or a topical decongestant. Therefore, the administration of a decongestant is suggested as prophylactic. The recitation "oxymetazoline nasal spray is little more effective than placebo" indicates there was some amount of efficacy in reducing ear and sinus blockage. Singletary also describes barotrauma, in the form of sinus pain, during descent on a commercial airline. The subject received both systemic and topical decongestants.

Claim 1 recites "ingesting a nasal decongestant at least one hour before the scheduled aircraft landing" and "applying a nasal decongestant into the nose later". An oral administration may occur prior to boarding the aircraft for a short flight. According to the claim language, the topical administration may follow at any time thereafter while in flight. Since barotrauma occurs during aircraft descent when the pressure in the

middle ear drops relative to that in the ear canal, prophylactic treatment for symptoms of ear and sinus blockage through oral ingestion of a decongestant may occur prior to boarding the aircraft.

In view of the combined teachings of Jones and Singletary, one skilled in the otolaryngology art would have been motivated to prepare a kit comprising both oral and aerosol decongestant products from among the very well established commercial products, phenylephrine, oxymetazoline and pseudoephedrine, that are known in the prior art for alleviating the symptoms of ear and sinus blockage. Since the time at which barotrauma occurs is on descent, and, since about an hour would be required to achieve effective absorption of the decongestant, nothing unobvious is noted in ingesting a nasal decongestant about one hour prior to landing. The determination of optimal dosages and dosing regimens are within the purview of those skilled in the art, with particular regard to the condition and medical status of the patient, through no more than routine experimentation.

No claim is allowed.

Capes et al., American Journal of Emergency Medicine, is cited to show further the state of the art with respect to prophylactic treatment modalities for barotrauma. Although not drawn to barotrauma that occurs as a result of air travel, the reference describes the prevention of otic barotrauma through the administration of both topical and systemic decongestants. See Table 2, page 646.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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June 4, 2006

Phyllis Spivack

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PHYLlis SPIVACK
PRIMARY EXAMINER
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